

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/806,703	STEINAA ET AL.	
	Examiner DiBrino Marianne	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Applicant's amendment after final filed 1/14/05.
2.  The allowed claim(s) is/are 69,86,89,92 and 95.
3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date attached hereto.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

## DETAILED ACTION

1. Applicant's amendment after final filed 1/14/05 is acknowledged and has been entered.
2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 69, 86, 89, 92 and 95 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 123-125 of copending Application No. 10/441,779. Although the conflicting claims are not identical, they are not patentably distinct from each other because the protein encoded by SEQ ID NO: 3 starting at amino acid residue 1 and including at least amino acid residue 654 includes a substantial part of all known and predicted CTL and B-cell epitopes of human Her2, and SEQ ID NO: 12 and 14 recited in instant claim 95 are tetanus toxoid T<sub>H</sub> epitopes encompassed by the tetanus toxoid epitope recited in claim 124 of '779.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. The provisional rejection of claims 69, 86, 89, 92 and 95 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 123-125 of copending Application No. 10/441,779 above, is HEREBY WITHDRAWN.

Given that a provisional double patenting rejection over copending Application No. 10/441,779 would be the only rejection remaining in this application, such a provisional obvious double patenting is withdrawn to permit this application to issue. See MPEP 804.

5. The reference listed on the accompanying form 892, Fidel et al (J. Exp. Med., 1983, Vol. 157, pages 1947-1957) is made of record by the Examiner to evidence that the limitation "*P. falciparum CS*" recited in instant claim 92 is a known term in the art at the time the invention was made, said limitation being equivalent to *P. falciparum* circumsporozoite.

#### **EXAMINER'S AMENDMENT**

6. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given by Dr. Susan Gorman on 3/14/05.

Permission was given by Dr. Gorman to extend time 2 months.

#### **In the claims:**

- a. In claim 69, -- the—has been added before "Her 2" at line 3 before "starting at", "starting at" has been deleted at line 3 before "SEQ", --protein encoded by— has been added before "SEQ" at line 3, and "or a deletion" has been deleted at the last line after the limitation "substitution" and before the period.
- b. In claim 89, --the group consisting of—has been added after "from" and before "a" at line 2.
- c. In claim 92, --the group consisting of—has been added after "from" and before "a" at line 2.
- d. In claim 92, "*P. falciparum*" has been italicized to "*P. falciparum*".
- e. Withdrawn claims 1-66 and 70-83 have been canceled.

## REASONS FOR ALLOWANCE

7. The following is an examiner's statement of reasons for allowance:
  - a. The provisional rejection of claims 69, 86, 89, 92 and 95 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 123-125 of copending Application No. 10/441,779 has been withdrawn to permit this application to issue as enunciated at item 4 of this Action supra (see MPEP 804).
  - b. Claims 69, 86, 89, 92 and 95 are pending and are allowable.
  - c. The claimed analogue of human Her2 which is immunogenic in humans, said analogue comprising continuous sequence of the Her2 protein encoded by SEQ ID NO: 3 starting at amino acid residue 1 and including at least amino acid residue 654, which is modified with at least one foreign T<sub>H</sub> epitope at one or more positions recited in the instant claims is not taught or suggested by the prior art.
  - d. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
8. Applicant is reminded that where an interview initiated by the Applicant results in the allowance of the application, the Applicant is advised to file a written record of the substance of the interview as soon as possible to prevent any possible delays in the issuance of a patent. See MPEP 713.04. With regard to this matter, the Examiner reminds Applicant of the Interview Summary form PTOL-413 attached hereto (Applicant initiated interview).
9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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